APR 1 4 2014

K130852

510(k) SUMMARY

This 510(k) summary of safety and efficacy information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: March 20, 2013

Submitter:

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Trade/Proprietary Name: Avance® Foam Abdominal Dressing Kits

Common Name: NPWT Dressing Kits

Classification Name: Powered Suction Pump and Surgical Mesh

Predicate Device Name(s): Avance® Foam Dressing Kits (K122132)
RENASYS™ AB Abdominal Dressing Kit (K112784)

Description of Device:

The Avance® Foam Abdominal Dressing Kit is a negative pressure wound therapy device intended to provide negative pressure to the wound bed and thereby transport exudates from the wound. The Avance® Foam Abdominal Dressing Kit is a combination of different components developed and arranged to meet the needs of the clinical for specific size and types of wounds.

The Avance® Foam Abdominal Dressing Kit is together with the Avance® Pump and it's accessories is a complete negative pressure system for managing open abdomens. This dressing kit is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

The Avance® Foam Abdominal Dressing Kit consists of the following components:

Avance® Organ Contact Layer (OCL) is based on an oval polyurethane film with fenestrations and is placed in the open abdomen to protect and contain intestines.

Avance® Abdominal Foam is placed over the OCL with the intention to distribute the pressure across the wound surface and allow passage of fluids and exudates through to the negative pressure system.
Avance® Film with Safetac® Technology 20x40 cm in size, is a flexible, transparent film dressing consisting of a thin polyurethane film coated with a soft silicone adhesive. The soft silicone layer adheres gently to dry peri-wound skin, but not to a moist wound surface. The soft silicone layer is covered with a polyethylene release film. It is applied over the wound filler and surrounding skin with the intension to fixate the wound filler and create an airtight seal.

Avance® Transfer Pad is intended to transport exudates from the abdominal cavity to the canister. A hole is cut in the sealant before attaching the Transfer Pad.

Intended Use/Indication for Use:

The Avance® Foam Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. Its intended use is with patients who have open abdominal wounds with exposed viscera and organs, and including but not limited to patients with abdominal compartment syndrome. It is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre. The dressing kit is intended for use together with the Avance NPWT pump and its accessories.

Performance Data:

The kit was tested in conjunction with the pump and the performance results were as follows:

- The vacuum level values measured in the wound model are within the chosen levels and shows a constant and uniform behavior.
- The fluid was efficiently transported from the wound model without blockage or problems.

The Avance® Foam Abdominal Dressing Kit was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

These tests were comprised of:

Drapability – Testing showed that all test articles were successfully subjected to the testing criteria for drapability. The predetermined acceptance criteria were met.
Tear Strength– Testing showed that all test articles were successfully subjected to the testing criteria for tear strength. The predetermined acceptance criteria were met.

Tensile Strength– Testing showed that all test articles were successfully subjected to the testing criteria for tensile strength. The predetermined acceptance criteria were met.

Fluid Transport– Testing showed that all test articles were successfully subjected to the testing criteria for fluid transport. The predetermined acceptance criteria were met.

Biocompatibility:

This table includes the testing criteria required as well as the test outcomes for the components within the Avance® Foam Abdominal Dressing Kit.

Avance® Foam Abdominal Dressing Kit Components
Biological Assessment Requirements for Testing based on ISO 10993

Component	Toxicological Evaluation under ISO 10993 for Product Categorization	Testing Outcome
Organ Contact Layer	• Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Acute Systemic Toxicity • Subchronic Toxicity • Genotoxicity • Implantation	• Met • Met • Met • Met • Met • Met • Met
Foam	• Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity	• Pass • Pass • Met
Transparent Film	• Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity	• Pass • Pass • Met
Transfer Pad	• Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity	• Pass • Pass • Met

Clinical Testing:

No clinical data was required.

Product Comparison to Predicate(s)

All of the kit components with the exception of the Organ Contact Layer have been cleared for use as a NPWT dressing kit under K122132. The components used in this abdominal dressing kit (with the exception of the Organ Contact Layer) are identical to those in material and function of the components cleared under K122132. The only difference in any one of those components is the size and shape of the foam.

The Avance® Foam Abdominal Dressing Kit has the same indication for use as the RENASYS™ AB Abdominal Dressing Kit (K112784) and the same types of kit components.

Conclusion:

Based on the information presented in this submission, it can be concluded that the Avance® Foam Abdominal Dressing Kit is substantially equivalent to the current Avance® Foam Dressing Kits (K122132) and the RENASYS™ AB Abdominal Dressing Kit (K112784) predicate(s) with respect to intended use, materials, design, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 14, 2014

Molylcke Health Care US, LLC
Ms. Angela L. Bunn, RAC
Director, Regulatory Affairs of the Americas
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

Re: K130852
Trade/Device Name: Avance® Form Abdominal Dressing Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXJ, OMP
Dated: February 24, 2014
Received: February 25, 2014

Dear Ms. Bunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130852

Device Name: Avance® Foam Abdominal Dressing Kit

Indications For Use:

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Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S